In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1517V

GLORIA SUPERNAW,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 10, 2024

Andrew D. Downing, Downing, Allison & Jorgenson, Phoenix, AZ , for Petitioner.

Eleanor Hanson, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On November 3, 2020, Gloria Supernaw filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her on September 28, 2019. Petition (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU"). As set forth in more detail below, I find that Petitioner more likely than not received the flu vaccine in her injured right arm. And based on the lack of any other objections from Respondent, along with an

[1] Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

independent review of the record, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim – making her entitled to compensation.

I. Procedural History

The November 2020 Petition was accompanied by Exhibits ("Exs.") 1 – 16 (ECF Nos. 1, 6 – 7, 20, 23). Respondent opposed compensation of the claim, on the grounds that Petitioner had not received a covered vaccine in her injured right arm. Rule 4(c) Report filed Aug. 17, 2022 (ECF No. 30).

Both parties were afforded a final opportunity to file briefs and any additional evidence they wished to have considered in my adjudication of the disputed site issue. Scheduling Order filed Nov. 7, 2022 (ECF No. 31); *see also* Ex. 17 (ECF No. 32); Petitioner's Brief Regarding Site of Vaccine Administration filed Feb. 9, 2023 (ECF No. 34) (hereinafter "Brief"); Respondent's Response filed May 25, 2023 (ECF No. 36) ("Response"); Petitioner's Reply filed June 28, 2023 (ECF No. 37) ("Reply"). The matter is now ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Finding of Fact and Conclusions of Law – Flu Vaccine Administration Site

I have reviewed all of the filings submitted by both parties to date, but focus the below summary on evidence most relevant to the disputed issue of the flu vaccine's administration site.

- On September 28, 2019, at a local Walgreens pharmacy, Petitioner[4] received Fluzone (flu) and Pneumovax 23 vaccines.[5] Ex. 10 at 2.
    - The Walgreens "Vaccine Administration Record (VAR) – Informed Consent for Vaccination" form for the flu vaccine contains a handwritten circle around the letter "L", indicating a *left* deltoid site of administration, followed by the immunizer's signature. Ex. 10 at 10 at 5 – 6.
    - Walgreens' VAR pertaining to the Pneumovax vaccine does not document a site of administration. Ex. 10 at 3 – 4, *see also id.* at 9 – 10.

[4] Prior to September 28, 2019, Petitioner "had no history of shoulder pain, inflammation, or dysfunction." Rule 4(c) Report at 2.

[5] To receive compensation under the Vaccine Act, a petitioner must show that he or she received a vaccine set forth in the Vaccine Injury Table (the "Table"). *See* § 11(c)(1)(A); 42 C.F.R. § 100.3. "There are two types of pneumococcal vaccines ... pneumococcal conjugate and polysaccharide vaccine[s]. The polysaccharide vaccine is distributed under the brand name Pneumovax." *Bundy v. Sec'y of Health & Hum. Servs.*, No. 12-0769V, 2014 WL 348852, at *1 (Fed. Cl. Spec. Mstr. Jan. 8, 2014). Only pneumococcal conjugate vaccines, routinely administered to children, are covered by the Vaccine Program. *Id.; see also Morrison v. Sec'y of Health & Hum. Servs.*, No. 04-1683V, 2005 WL 2008245, at *1 (Fed. Cl. Spec. MStr. July 26, 2005) (describing how and when pneumococcal conjugate vaccines were added to the Vaccine Table). Thus, Pneumovax (pneumococcal polysaccharide) vaccines are not included on the Table, and cannot be the basis for a Program claim.

- Also on September 28, 2019, via text message,[6] Petitioner stated that after receiving her flu and Pneumovax vaccines that afternoon, she had developed severe soreness in both arms. Ex. 14 at 1. Petitioner stated that the vaccines were given very high and bilaterally. *Id.* at 1, 3. On September 29, 2019, Petitioner stated: "my pneumonia arm is still sore but not the flu one." *Id.* at 4.

- Thirty-seven (37) days post-vaccination, on November 4, 2019, at Sierra Pacific Orthopedics, Petitioner attended a follow-up appointment for an unrelated issue. These records did not include any information about her recent vaccinations or any right shoulder injury. Ex.9 at 23 – 25.

- Eighty-six (86) days post-vaccination, on December 16, 2019, at the Simonian Sports Medicine Clinic, Petitioner attended her first follow-up appointment for a second unrelated issue. Ex. 4 at 15; *see also id.* at 16 – 17, 49 – 50. During this appointment, Petitioner also complained of right shoulder pain "that started after a flu shot" that was administered "rather high near to her acromion." Ex. 4 at 15. Peter T. Simonian, M.D., documented decreased range of motion ("ROM") and tenderness at the acromioclavicular ("AC") joint, tentatively assessed as impingement, inflammation, and adhesive capsulitis. *Id.*

- Also on December 16, 2019, an MRI of the right shoulder visualized AC joint arthrosis, and bursal surface tearing at the junction of the supraspinatus and infraspinatus tendons. Ex. 4 at 75.

- On December 23, 2019, Dr. Simonian administered a cortisone injection and referred Petitioner to physical therapy ("PT") for her right shoulder. Ex. 4 at 14.

- At a January 6, 2020, PT initial evaluation, Petitioner again attributed her right shoulder injury to the "flu vaccination" she had received in September 2019. Ex. 6 at 2. She a total of 5 PT sessions that month. *See generally* Ex. 13 at 316 – 48.[7]

[6] Respondent requests that Petitioner file certified copies of the text messages from her cell phone provider. Rule 4(c) Report at n. 2; *see also* Response at n. 2. Petitioner avers that she has provided sufficient documentation of the text messages, they are authentic, Respondent has not actually disputed their authenticity, and any such dispute would be unwarranted here. Reply at 5. I find that Petitioner has supplied enough documentation of the text messages to be reasonable and necessary for adjudication of the current dispute.

[7] Dr. Simonian directed all subsequent treatment of Petitioner's right shoulder injury – including a February 2020 arthroscopic surgery, post-operative follow-up appointments; an initial post-operative PT evaluation; a repeat MRI; one platelet-rich plasma injection, and a repeat steroid injection. Ex. 4 at 5, 10 – 13, 43 – 48, 63 – 64, 95 – 105, 110 – 120; Ex. 16 at 3. These records do not contain further histories or other information relevant to the disputed vaccine administration site issue, however.

- In a letter dated and sent to Walgreens on June 28, 2020, Petitioner advised that from her review, both VARs were both incomplete and incorrect. Ex. 17 at 1. Petitioner stated: "I asked the pharmacist which drug was being given into which arm[.] She verbally told me she was injecting the pneumonia vaccine into my left shoulder, proceeded to administer it[,] and then she said she was injecting the influenza into my right shoulder." *Id.* Petitioner asked Walgreens to amend the records to correct these "errors… pursuant to [her] patient rights under [HIPAA] and Walgreens' Notice of Privacy Practices." *Id.*

- I have also reviewed Petitioner's October 3, 2020, declaration (Ex. 1).[8] In relevant part, Petitioner recalls that the Walgreens pharmacist seemed disorganized, took substantial time to gather the necessary paperwork, and told Petitioner to sit in the public retail area rather than behind a privacy screen. *Id.* at ¶¶ 3 – 4. In response to Petitioner's specific questioning, the pharmacist narrated administering the Pneumovax vaccine into her left arm, followed by the flu vaccine in her right arm. *Id.* at ¶ 4. Petitioner also states that she first obtained copies of the VARs in April 2020. *Id.* at ¶ 13.

- On August 18, 2021, the state pharmacy board advised that "its review of an investigation… initiated by [Petitioner's] complaint" was complete. Ex. 15 at 1.[9] As a result of that investigation, the board concluded that the immunizing pharmacist[10] had engaged in unprofessional conduct, including "disregard[ing] Walgreens policies and procedures for immunization. She should have indicated on the [VAR] which site the Pneumovax 23 vaccination was administered in, and this place was left blank on the form." *Id.* at 7. The pharmacist also utilized an "incorrect vaccination technique resulting in shoulder injury" (but "due to incomplete information on the VAR, it is not possible to determine if [the injurious vaccine] was Fluzone HD or Pneumovax 23)." *Id.* at 6. The pharmacist also failed to provide documentation of the vaccinations to Petitioner, and to her primary care provider

[8] Respondent notes that Petitioner's declaration is not notarized. Response at 5. However, Petitioner's declaration is sworn under penalty of perjury. Ex. 1 at 2; *see also* 28 U.S.C.A. § 1746 (providing that such a declaration may be afforded like force and effect as a notarized affidavit).

[9] After reviewing Ex. 15, Respondent requested "copies of *all* documents, correspondence, and communications between Petitioner, Walgreens, and the California State Board of Pharmacy concerning alleged pharmacist misconduct as it relates to the vaccinations administered to Petitioner on September 28, 2019." Rule 4(c) Report at n. 3 (emphasis added). Petitioner did not address this request, and it was not renewed by Respondent. *See generally* Brief; Response; Reply.

[10] Based on the submitted evidence (and lack of argument from the parties), I find it more likely than not that the Walgreens VARs (*see generally* Ex. 10) and the state pharmacy board citation (Ex. 15 at 6 – 7) identify the same pharmacist, despite utilizing different first names.

("PCP"). *Id.* at 6 – 7.[11] The pharmacist was ordered to either pay a $1,000.00 fine, or a lesser fine of $500.00 and complete three hours of remedial education in immunization. *Id.* at 7 – 8.[12]

The only issue requiring adjudication is the covered flu vaccine's administration site. My experience with SIRVA cases (over 2,000 within SPU since my appointment as Chief Special Master, additional cases handled within chambers, and review of opinions issued by other special masters) teaches that it is not unusual for information regarding the vaccine administration site to be incorrect – especially information contained in *computerized* records, which may feature a 'dropdown' menu which may not be updated each time a separate vaccine is administered.[13]

By contrast, however, information which requires *specific action* on the part of the vaccine administrator (often at the very time of administration), such as a handwritten notation on a printed form, *generally* warrants more significant weight.[14] But the implications of handwritten notations can be rebutted by additional, case-specific evidence and circumstances.[15]

Here, Petitioner claims a right-sided SIRVA – requiring evidence that a covered vaccine was administered in her right arm. But the handwritten notation from the VAR indicates the flu vaccine was administered in her *left* arm. This VAR appears complete and reliable, when viewed in isolation. Petitioner notes, however, that the VAR for her concurrent, non-covered Pneumovax vaccine does *not* document situs, and this (plus other evidence) suggest the VAR is not completely reliable on the issue of situs. Brief at 15 – 16.

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[11] *Accord* Ex. 2 at 4 – 5 (PCP records, not reflecting the at-issue vaccinations).

[12] The state pharmacy board also issued a letter of admonishment to the pharmacist-in-charge, and a citation to the Walgreens location, Ex. 15 at 2 – 5, but those did not involve any fines or remedial education.

[13] *See, e.g.*, *Mezzacapo v. Sec'y of Health Servs.*, No. 18-1977, 2021 WL 1940435, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 2021); *Desai v. Sec'y of Health & Human Servs.*, No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); *Rodgers v. Sec'y of Health & Human Servs.*, No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *Stoliker v. Sec'y of Health & Human Servs.*, No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018).

[14] *See, e.g.*, *Schmidt v. Sec'y of Health & Hum. Servs.*, No. 17-1530V, 2021 WL 5226494, at *8 (Fed. Cl. Spec. Mstr. Oct. 7, 2021); *Marion v. Sec'y of Health & Hum. Servs.*, No. 19-0495V, 2020 WL 7054414 at *8 (Fed. Cl. Spec. Mstr. Oct. 27, 2020).

[15] *See, e.g.*, *Toothman v. Sec'y of Health & Hum. Servs.*, No. 22-0207V, 2024 WL 2698520, at *4 (Fed. Cl. Spec. Mstr. Apr. 19, 2024); *Rizvi v. Sec'y of Health & Hum. Servs.*, No. 21-0881V, 2022 WL 2284311 at * 3 (Fed. Cl. Spec. Mstr. May 13, 2022).

In response, Respondent contends that the record of a left-sided flu vaccine administration has not been rebutted by "preponderant evidence in the form of testimony, written statements, or other medical records." Response at 10. Petitioner's "complaints to, and subsequent citations issued from, the [state pharmacy board…] are based solely upon Petitioner's statements, and not upon independent information or other objective evidence." *Id.* But after receiving Petitioner's complaint, the state pharmacy board in fact conducted *its own* "review" and "investigation." Ex. 15 at 1. The board then issued conclusions that the immunizing pharmacist had failed to record the Pneumovax vaccine's site of administration; improperly administered one or more vaccines; failed to provide documentation of the vaccinations to Petitioner and her PCP. Based on these conclusions, the board took disciplinary action against the immunizing pharmacist (and to a lesser extent, the pharmacist-in-charge, and the Walgreens store location). *Id.* at 6 – 8. This constitutes independent evidence undermining the reliability of both VARs.

The state pharmacy board's conclusions are further *corroborated* by two medical providers' records from about three months post-vaccination, at which time Petitioner attributed her ongoing right shoulder injury to the flu vaccine. The Federal Circuit has counseled that. patient histories "in general, warrant consideration as trustworthy evidence… [as they] contain information supplied to… health professionals to facilitate diagnosis and treatment." *Cucuras*, 993 F.2d at 1528. Petitioner's declaration provides additional, consistent details about the pharmacist's conduct.

I have also considered Respondent's argument that Petitioner's text messages weaken her site allegations. Response at 10 (citing Ex. 14 at 4 (providing that "my pneumonia arm is still sore but not the flu one")). In response, Petitioner persuasively explained that the reported improvement of pain approximately 24 hours post-vaccination did not preclude the possibility of a subsequently more persistent injury, let alone where the flu vaccine was most likely administered. The text messages do not warrant particular weight in establishing each vaccine's site of administration.

Overall, the flu vaccine's VAR is the *only* evidence supporting a finding that it was administered in Petitioner's left arm. All other evidence collectively supports a finding of the flu vaccine's administration in her right arm, as alleged. At worst, this factual dispute is a "close call," which should be resolved in Petitioner's favor.

Conclusion and Scheduling Order

Respondent does not raise any other objections to entitlement (*see generally* Rule 4(c) Report), and based on my independent review, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim. 42 C.F.R. §§

100.3(a), (c)(10). Accordingly, she need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other requirements of Section 11(c) including a sufficiently severe injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).[16]

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a right-sided SIRVA following the right-sided administration of the flu vaccine on September 28, 2019.** Therefore, the case is now formally in the damages phase.

By no later than Monday, August 26, 2024, Petitioner shall file a Status Report updating on the parties' efforts towards informally resolving damages – specifically including the date on which Respondent responded to the previously-submitted demand, *see* Status Reports (ECF No. 22, 25). If Respondent has not yet responded, the parties shall confer, and Petitioner shall report the date by which Respondent expects to respond.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[16] The parties did not request determination of the non-covered Pneumovax vaccine's site of administration. That fact would be more difficult to determine, given the undisputed lack of contemporaneous documentation. However, even if it were found that Petitioner received *both* a covered flu vaccine and non-covered Pneumovax vaccine in her injured right arm, that would not obviously bar entitlement for a SIRVA. *See, e.g.*, *Kalail v. Sec'y of Health & Hum. Servs.*, No. 20-0593V, 2022 WL 4115755 (Fed. Cl. Spec. Mstr. Aug. 8, 2022) (approving Respondent's concession of entitlement notwithstanding concurrent administration of Tdap and Pneumovax vaccines); *Hustead v. Sec'y of Health & Hum. Servs.*, No. 20-1212V, 2021 WL 5775149 (Fed. Cl. Spec. Mstr. Nov. 3, 2021) (involving flu, Tdap, and Pneumovax vaccines).